OCT 16 2003

K031966

COOK®

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510(k) SUMMARY

Submitted By:	COOK INCORPORATED 750 Daniels Way Bloomington, In 47404
Contact:	Jennifer Bosley, MBA Regulatory Affairs Coordinator Tel: (812) 339-2235 Fax: (812) 332-0281
Date Prepared:	June 25, 2003
510(k) #:	
Device:	
Trade Name:	Enk Fiberoptic Atomizer Set
Common/Usual Name Proposed	Laryngo-Tracheal Topical Anesthetic Applicator
Classification Name:	(1) Applicator (Laryngo-Tracheal), Topical Anesthesia, 21 CFR § 868.5170 (2) Accessory to Bronchoscope, 21 CFR § 874.4680
Class:	Class II
Product and Panel Code:	(1) CCT—73—Anesthesiology Device Panel (2) KTI—77—Ear Nose & Throat Device Panel

Intended Use:
The Enk Fiberoptic Atomizer Set is a topical anesthesia applicator used to apply topical anesthetics to a patient's laryngo-tracheal area through the working channel of the bronchoscope using oxygen flow. The sterile one-time use device is designed and intended to be used by physicians trained and experienced in flexible fiberoptic intubation techniques.

Predicate Device:
The subject device is similar to the predicate device in terms of intended use, and general material composition. Any differences that may exist do not significantly affect the safety and effectiveness of the device.

MANUFACTURER	DEVICE	510(K) NUMBER
Wolfe Tory Medical	Laryngo-Tracheal Mucosal Atomization Device (MADgic™)	K002255

Device Description:
The Enk Fiberoptic Atomizer Set consists of a pressure resistant oxygen tube and a connecting tube connected by a three-way side-arm fitting with a small flow control opening. The set also contains an introducer catheter and two 1 ml syringes.

Substantial Equivalence:
The subject device is similar with respect to indications for use and design features to the predicate device in terms of section 510(k) substantial equivalence.

Test Data:
Performance testing, which includes tightness, air flow and tensile testing, provides reasonable assurance of safety and effectiveness for the device's intended use as an applicator for laryngo-tracheal topical anesthesia.

COMPARISON TO PREDICATE DEVICE

Device	COOK Enk Fiberoptic Atomizer Set (Subject of Submission)	Wolfe Tory Medical MADgic™ Laryngo-Tracheal Mucosal Atomization Device (K002255)
Reg No./Code	868.5170—CCT 874.4680—KTI	868.5170—CCT
Intended Use	The Enk Fiberoptic Atomizer Set is a topical anesthesia applicator used to apply topical anesthetics to a patient's laryngo-tracheal area through the working channel of the bronchoscope using oxygen flow. The sterile one-time use device is designed and intended to be used by physicians trained and experienced in flexible fiberoptic intubation techniques.	Intended for the application of topical anesthetics to the oropharynx and upper airway region.
Materials	Polyurethane	Polycarbonate and Polyvinyl chloride
Method of Operation	Delivery form is a spray mist using oxygen flow through a bronchoscope. Device does not come into direct contact with patient.	Delivery form is a fine spray mist generated by piston syringe. Device comes into direct contact with patient.
Specifications	225cm oxygen tube, 9.5 Fr	8 inch malleable stylet
Accessory Status	Device is an accessory to a bronchoscope.	n/a
Reuse	One-Time Use	One-Time Use
Sterility	Sterile	Individually packaged clean

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2003

Cook Incorporated
c/o Jennifer Bosley, MBA
PO Box 489
Bloomington, IN. 47402-0489

Re: K031966
Trade/Device Name: Enk Fiberoptic Atomizer Set
Regulation Number: 874.4680
Regulation Name: Bronchoscope and accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: September 25, 2003
Received: September 26, 2003

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the performance of topical anesthesia of the lower airways (below the level of the trachea) have not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the

market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031966

Device Name: Enk Fiberoptic Atomizer Set

FDA's Statement of the Indications for Use for device:

The Enk Fiberoptic Atomizer Set is a topical anesthesia applicator used to apply topical anesthetics to a patient's laryngo-trachea area through the working channel of the bronchoscope using oxygen flow. The sterile one-time use device is designed and intended to be used by physicians trained and experienced in flexible fiberoptic intubation techniques.

The safety and effectiveness of this device for use in the performance of topical anesthesia of the lower airways (below the level of the trachea) have not been established.

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K031966